K110288

510(k) Summary for the FemVue™ Saline-Air Device

APR 2 8 2011

Date of Summary:	March 25, 2011
510(k) Submitter and Primary Contact:	Lisa Peacock Vice President, Regulatory Affairs Femasys Inc. 5000 Research Court Suite 100 Suwanee, GA 30024 Tel: 770-500-3910 Fax: 770-500-3980 LPEACOCK@FEMASYS.COM
Device Common Name:	Contrast media syringe (as an accessory to an intrauterine catheter)
FDA Device Classification Name:	Cannula, Manipulator/Injector, Uterine
Product Code:	LKF
Classification Regulation:	Unclassified
Device Class:	Unclassified, Pre-Amendment 510(k) Submission
Panel:	Obstetrics/Gynecology
Indication for Use:	The FemVue Saline-Air Device instills a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).
Device Description:	The FemVue™ Saline-Air Device is a dual-barrel contrast media syringe that can be connected to an intrauterine catheter to instill saline-air contrast media during sono-hysterosalpingogram (Sono HSG) procedures. Sono HSG consists of an ultrasound evaluation of the fallopian tubes with or without assessment of the uterine cavity.
Predicate Device:	Ackrad H/S Elliptosphere Procedure Tray K020954

Summary of Testing: The FemVue was tested by the following non-clinical methods to demonstrate that the device is substantially equivalent to the predicate device in functionality, safety, and effectiveness:

- Fluid and air instillation function of syringe
- Catheter attachment
- Single-hand actuation
- Delivers continuous and consistent stream of an alternating pattern of saline and air

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

APR 28 2011

Ms. Lisa Peacock
VP, Regulatory Affairs
Femasys, Inc.
5000 Research Court, Suite 100
SUWANEE GA 30024

Re: K110288
Trade/Device Name: FemVue™ Saline-Air Device
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: March 25, 2011
Received: March 28, 2011

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110288

Device Name: FemVue™ Saline-Air Device

Indications for Use:

The FemVue™ Saline-Air Device instills a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110288